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#### Rationale and objective

Women who are invited for breast cancer screening should get enough information about the benefits and harms of screening to make an informed decision on participation. Personal invitations are an important source of information as all invited women receive them. The objective was to evaluate the information breast cancer screening units send to women invited for screening in Finland.

#### Materials and Methods

A questionnaire was sent to all breast cancer screening units in 2005 and in 2008 in Finland and the information (e.g. invitations, result letters, leaflets) the units sent to women were collected. Results from 2005 were sent as feedback to the units. Data were analysed descriptively and results from the two years were compared.

#### Results

Screening units sent personal invitation letters usually providing a fixed appointment time. Most units informed about participation free of charge and benefits of detecting breast cancer early. Harms associated with screening were seldom mentioned; no unit presented the possibilities of false negative results or over-treatment.

#### Conclusion

The screening units provided very variable information which often was biased towards optimizing participation. The high participation rate (approximately 88%) in Finland may partly be due to the prescriptive nature of the invitation letters. National templates for information letters would be useful.

**Keywords:** Breast cancer, Screening, Invitation, Informed consent

## Personal invitations for population-based breast cancer screening

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# Text

## Background

Breast cancer screening programme aims at reducing mortality from breast cancer. Mammography screening can detect tumours at a preclinical stage, providing possibility for early treatment of cancer. Earlier diagnosis may improve the prognosis and reduce need for invasive treatment. The limitations of mammography screening include false-positive and false-negative mammograms, over-diagnosis, increased anxiety for screened women, and harms from radiation.

In Finland, legislation requires municipalities to arrange breast cancer screening biannually for women aged 50-69. The nationwide screening started gradually for women aged 50-59 in 1987 and covered the whole country in early 1990s. In 2006 the screening programme was expanded to include women 60-69 years of age. The screening and further investigations are free of charge for all participants. Municipalities can provide screening in their own screening unit or purchase it from commercial providers. The screening centres in Finland partly fulfil the process criteria given in the guidelines of the European Community (Table 1).

In many countries, information concerning screening mammography presented on websites and screening invitations is insufficient (1). According to Finnish legislation, women invited for breast cancer screening should obtain adequate information about the benefits and harms of screening in order to make an informed decision about participation. Personal invitations are an important source of information, as the entire target group receive these. In Finland, municipalities have autonomy over the screening process of administering population-based cancer screening. They are responsible for ensuring the quality of the screening process, including the content of invitations and letters notifying women of a normal or abnormal result.

We sought to evaluate the content of screening mammography invitations and result notification letters across the country to assess the sufficiency of information provided.

## **Methods**

The Finnish Office for Health Technology Assessment (Finohta) surveyed the information offered by the screening units to women invited to mammography screening in Finland as part of an HTA report (2). In September 2005, we mailed an inquiry to all breast cancer screening units in Finland, using addresses received from the Finnish cancer registry. A reminder was sent to units which didn't answer to the first letter. The units were asked to send us their invitation and result letters and all other information offered at different stages to persons invited for screening.

We informed the screening units about their practices by sending them the HTA report which included the results of the 2005 survey (2) with a personal cover letter. The main results were also published in the newsletter for radiographers and Finohta's newsletter *Impakti* for municipal decision-makers.

The survey was updated in November 2008. The National Screening Board at the Ministry of Welfare and Health requested this update to evaluate changes in the content of invitations. The inquiry was sent in a similar manner as before to all screening units.

We evaluated the information policy of screening units by analysing the invitation letters for screening and for further investigations (additional mammography, ultrasound, fine needle biopsy, surgery), as well as the letters informing about results. We looked for items describing the

implementation and effectiveness of screening, and questions about risk factors and symptoms. We also asked about the invitation method the units used (e.g. open invitation without date or invitation with a fixed appointment time), methods they used to invite for further investigations (e.g. phone call or invitation letter), about differences in invitations for the first screen and the subsequent screens, and whether the units sent reminders. We classified the contents (effectiveness of breast cancer screening, methods of screening, questions about breast symptoms) and listed the items mentioned. We analysed the data using frequencies and did a qualitative analysis of the open questions. This article focuses on the invitations and normal result letters.

## **Results**

Over a decade, the screening technology has changed from conventional screen-film to digital mammography. This resulted in some changes of providers in Finland: there are fewer municipal screening units while the number of private screening units has increased.

The inquiry was sent to all breast cancer screening units in Finland. In 2005 we sent the inquiry to 27 units and received answers from 23 units (85%), 10 of these after one reminder. In 2008, all 26 units responded, 12 after the reminder. They also sent information materials as requested (Table 2).

### *Invitation letters*

In 2005 all screening units and in 2008 all but two units sent a personal invitation letter with a fixed appointment time. All units sent similar invitation letters both for women invited for the first time and for subsequent screenings. In 2005 four units (17%) and in 2008 two units (7%) sent a detailed information leaflet on screening mammography when inviting women for the screening programme for the first time. The contents of the invitation letters are summarised in the table 3.

In 2005 every fourth screening unit (26%) and in 2008 15% of screening units mentioned in their invitation the prevalence of breast cancer. The prevalence was usually given without numbers, as “high” or “most common”. Many invitation letters included questions about symptoms suggestive of breast cancer, for example lumps (in 2005 65%, in 2008 77%), leakage (61% vs. 69%), previous operations (65% vs. 73%), and previous breast cancer (57% vs. 62%). In 2005, 57% of the screening units asked if the woman used hormonal treatment, while in 2008 most units (81%) asked about this and every third unit had additional questions about the therapy (product used and duration).

Almost all screening units' invitations told that the participation is free of charge. Most units remarked that screening enables an early detection of breast cancer and that women participating in screening have better prognosis (see table 3). The effectiveness of screening was rarely mentioned; only 17% of the invitation letters in 2005 informed about the positive predictive value and specificity of mammography screening. Three years later, positive predictive value and specificity were given by two letters only (7% of units). In 2005, letters often specified that benign lesions can be found in the screening mammography (74%), but three years later less than half of the units (42%) referred to this. The possibility of a false negative result was not mentioned any invitation letter either year. Harms related to breast cancer screening were seldom mentioned; in 2005, four invitation letters (17%) told that mammography may be painful and in 2008 only three units (12%). The most important harms – overdiagnosis and overtreatment – were not mentioned in any invitation letter either year.

### *Result letters*

Women were usually informed about a normal result by letter. In 2008, one screening unit didn't send normal result letters at all, but called only those who were invited for further investigations. Most letters (96%) simply stated ‘no sign of cancer has been found’. The women were encouraged

to undertake regular breast self-examination (in 2005 96%, in 2008 92%) and to see a doctor if any unusual symptoms occur (100% vs. 96%); the ‘unusual symptoms’ were, however, not explained.

Most screening units (in 2005 91%, in 2008 93%) informed about a positive result primarily by phone, but only two units had guidelines for the content of this phone call. Two screening units sent the positive result merely by mail; in 2005 twelve units and in 2008 eight units sent a letter only if the woman couldn’t be reached by phone. These letters contained very little information. In 2005 eight units and in 2008 six units mentioned that most findings turn out to be benign. In 2005 only five units told that further investigations are free of charge while in 2008 this was said more often (14 units). The letters usually included a phone number for making an appointment; in 2005 four letters and in 2008 two letters included a phone number to use if the woman wished to obtain more information.

## **Discussion**

According to the guidelines of the European Union, women invited for screening should be fully informed about the benefits and risks (3). The evaluation of benefits and harms should be holistic in order to reflect consumer priorities (4). Informed consent can be supported by adequate information provided before and during the screening. Objective information is important as women easily overestimate the effectiveness of screening (5), and women who overestimate the benefits are known to participate more actively in screening (6).

The pros and cons of screening mammography can be presented using age-specific estimates, giving women, clinicians and service providers more information about screening (7,8). One way to give information is to present benefits and harms graphically, based on national screening results.

Figure 1 demonstrates the overall effect of breast cancer screening in Finland for women invited for



screening over the course of one year. This visual information can help women to consider the question “What could happen to me if I participate in screening?”

The data for Figure 1 originate mainly from the Mass Screening Registry in Finland. Data on participation and further investigations (additional mammography, ultrasound, fine needle biopsy, surgery) are means for a five-year period (1999-2003) in women aged 50-59 years. The interval cancer rate of breast cancer screening describes the number of cancers not detected (9). We calculated the outcome of breast cancers which can be prevented by screening using the average mortality rate of Finnish women aged 50-79 (75/100 000) and the average mortality rate from breast cancer (22%) from the meta-analysis of USPSTF (10). In Finland, breast cancer screening by mammography can thus annually prevent 16.5 breast cancer deaths per 100 000 women invited for screening. In other words, breast cancer screening can annually prevent one breast cancer death per 6060 women in the target group.

The content of invitation letters in Finland was changed somewhat over three years. At both times, we found wide variation between the screening units in the information they provided. The amount of detailed information decreased also because the screening units increasingly sent invitations centrally, using electronic address systems, which prevented the addition of information leaflets.

The information was biased towards optimizing participation, as most units mentioned the possibility of early detection and better prognosis while omitting exact information about incidence. Unfortunately, the information doesn't support an informed decision about participation in screening. There is clearly a need for better information in the invitation letters.

Our intervention consisted of requesting the information materials, analysing their contents, and feeding the summary results back to screening units. This did not improve the quality of the letters. During the study years, the mammography technology changed from analogue (film-based) to digital imaging, and this resulted in changes of providers as well. The market shift may have influenced the capacity and willingness of the units to improve their information materials.

The high participation rate in Finland may partly be due to the prescriptive nature of invitation letters. The participation rate can be annually followed through registers and it is possible to see whether more transparent information will have an effect on the participation rate.

As the municipalities are responsible for the quality of the screening process, they should ensure that the information materials are sound and unbiased. The National Screening Board could advise the units by providing sample information materials for their use. This will be the next step in Finland: Finohta is preparing sample letters for each stage of the screening process at the request of the Board. Such templates will support an equitable provision of services and the possibility of true informed consent while retaining municipal autonomy.

Figure 1. Annual general effect of breast cancer screening for 50-59-year-old women in 1999-2003 in Finland.

Table 1. Performance indicators of breast cancer screening programmes in Finland and Netherlands as compared to the guidelines of the European Community

Table 2. Information in the invitation letters (per cents of the screening units in Finland providing facts on each item)

Table 3. The analysed materials (invitation letters, remind letters, result letters and other materials) sent by the screening units

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**Table 1. Performance indicators of breast cancer screening programmes in Finland and Netherlands compared with the guidelines of the European community**

Performance Indicator	Finland 50-69 years	Netherlands 50-69 years	EU Guidelines (desirable level)
Attendance rate	90%	79%	>75%
Recall rate for further assessment	4.6%	1.3%	<5%
Breast cancer detection rate	2.74xIR*	2.95xIR*	>3xIR*
Proportion of screen-detective cancers that are carcinoma in situ	10%	14%	10-20%
Proportion of screen detected cancers at stage II	33%	20%	<20%
Proportion of screen detective invasive cancers that are node-negative	>70%	67%	76%
Begingn to malignant biopsy rate	<0.5:1	1:1	0,5:1
* IR Incidence rate			

Sarkeala T. et la. (2004)

**Table 2. Information in the invitation letters (per cents of the screening units in Finland providing facts on each item)**

Item	2005 N=23	2008 N=26 units
Prevalence of breast cancer	26%	15%
Early detection	83%	96%
Better prognosis	78%	88%
Possibility of benign lesions	74%	42%
Positive predictive value	17%	7%
Specificity of screening	17%	7%
Free of charge	96%	96%
Voluntary participation	9%	7%
Painful procedure	17%	12%
Hormonal therapy	57%	81%

**Table 3. The analysed materials (invitation letters, remind letters, result letters and other materials) sent by the screening units**

Material	2005 (23 units)	2008 (26 units)
Invitation letters	23	26
Reminder letters	7	9
Normal result letter	23	25
Invitation for further investigations	14	10
Other (leaflet)	4	2
Total	71	72





Ulla Saalasti-Koskinen

31.1.2009

Chief Editor  
Academic Radiology

Enclosed please find our reviewed manuscript "Personal invitations for population-based breast cancer screening" for possible publication in the Academic Radiology's special issue on Patient Centred Radiology.

We thank for the useful comments from reviewers. We have made the major changes as suggested: We edited the title, were more explicit on methodology, described the Finnish screening program in more detail, included comparative data from our 2008 survey and added two tables. This lengthened the article as reviewer #1 requested. Smaller specifically suggested changes (Reviewer #2) were handled as follows:

#### Background:

1. Please make the background section a distinct section separate from the methods: **Done**
2. Recommend expansion of the background section as many radiologists may not be familiar with the topic. Suggest the following:
  - a. Brief description of benefits and potential harms of breast cancer screening, including information specific to Finland compared to other populations: **Done**, added Table comparing to EU standards and the Netherlands
  - b. Move paragraph describing population-based cancer screening requirements by law: **Done**
  - c1. Para beginning Women invited: Suggest rewriting to link with opening paragraph: **Done**
  - c2. Also suggest noting individual municipalities' autonomy: **Done**
  - d. End with statement of purpose: **Done**

#### Methods:

1. Please make the methods section distinct. This section would appropriately start with the current paragraph 3: **Done**
2. Was the inquiry written? What were the efforts made to increase participation (eg. second invitation, follow up phone calls, financial rewards)?: **Added**
3. Please specify what month in "autumn 2005" was the survey conducted: **Done**
4. Please clarify "information policy": **Done**, expanded the last paragraph in Methods
5. Please clarify "further investigations": **Done**, last paragraph in Methods
6. Please clarify "the way the results were presented". What specific information did you evaluate? **Done**, last paragraph in Methods
7. Would descriptive statistics be useful? E.g. confidence intervals around the most important domains of information: **Not done**, as changes are small anyway and we do not conclude changes took place. If the Journal would prefer confidence intervals in Table 3 we will be happy to add them.



Ulla Saalasti-Koskinen

31.1.2009

Discussion:

1. The authors note that the content of the invitation letters were changed in the light of the survey results. Please describe the changes, eg. standardization of letters and notification protocols, standardized language: **Done**. The discussion has been rewritten and expanded. Not clear changes were observed.
2. When were the invitation letters changed? **Not done** (no changes observed).

Figure:

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Yours sincerely,

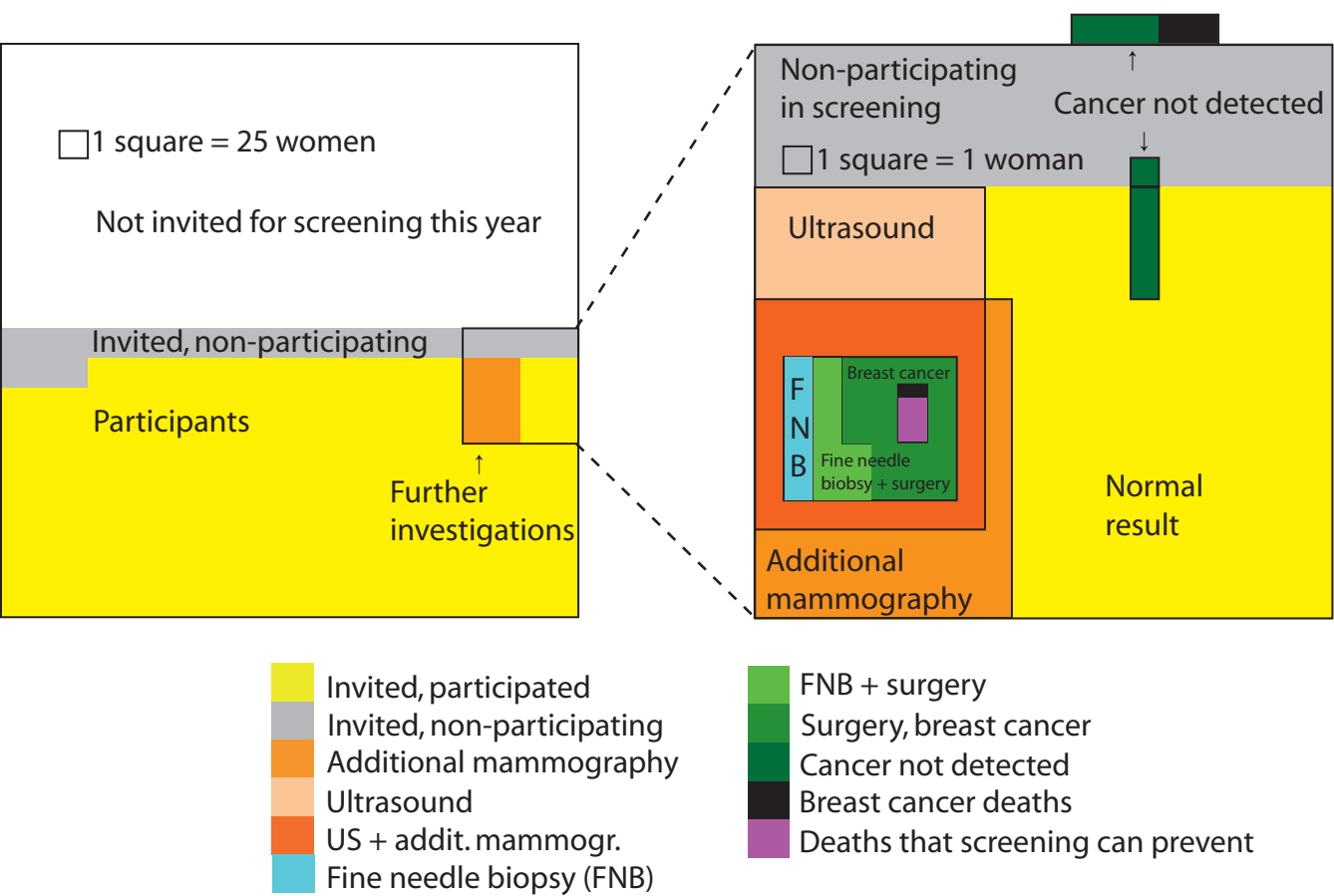
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Figure





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